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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/717,057	11/21/2000	Michael Brines	10165-010-999	5119

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EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/717,057	BRINES ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-7 and 9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-7 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 November 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 25 January 2005 has been entered.

Status of Application, Amendments and/or Claims

The amendment filed 25 January 2005 has been entered in full. Claims 1, 8, 10 and 11 are cancelled. The amendment recites, "amend claims 2-7, 9 and 12 are shown below". It is noted that claim 12 has not been added. Claims 2-7 and 9 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, First Paragraph, Scope of Enablement

Claims 2-7 and 9 remain rejected under 35 U.S.C. 112, first paragraph, scope of enablement.

the specification, while being enabling for:

a method of enhancing the function of **normal, damaged or injured excitable tissue** in a mammal, **wherein the damage or injury is caused by stroke**, comprising administering peripherally to a mammal in need thereof a non-toxic effective amount of recombinant erythropoietin for enhancing excitable tissue function; (claim 2) so that the associative learning or memory in/of the mammal is enhanced; (claim 3) so that cognitive function is enhanced.

a method of enhancing the function of **normal, damaged or injured excitable tissue in a mammal, wherein the damage or injury is caused by stroke, diabetic neuropathy or autoimmune encephalomyelitis**, comprising administering peripherally to a mammal in need thereof a non-toxic effective amount of recombinant erythropoietin for enhancing excitable tissue function; (claims 4) wherein said excitable tissue is central nervous system tissue or peripheral nervous system tissue; (claim 5) wherein said administration comprises oral, topical, intraluminal or by inhalation or parental administration; (claim 7) wherein said administration is acute or chronic; (claim 9) wherein said EPO is administered at a dose greater than the dose necessary to maximally stimulate erythropoiesis.

does not reasonably provide enablement for:

a method of enhancing the function of **damaged or injured excitable tissue** in a mammal, comprising administering peripherally to a mammal in need thereof a non-toxic effective amount of recombinant erythropoietin for enhancing excitable tissue function; so that the associative learning or memory in/of the mammal is enhanced; so that cognitive function is enhanced.

a method of enhancing the function of **normal, damaged or injured excitable tissue in a mammal**, comprising administering peripherally to a mammal in need thereof a non-toxic effective amount of recombinant erythropoietin for enhancing excitable tissue function.

The basis for this rejection is set forth at pages 2-4 of the previous Office Action (26 October 2004).

Applicant submits that the Examiners indicated in the Personal Interview (22 November 2004) that the amended claims would be favorably considered in light of the submission of references (Ehrenreich *et al.*, Bianchi *et al.* and Agnello *et al.*) showing the successful use of EPO to enhance function of damage tissue. Applicant states that Ehrenreich *et al.* peripherally administered high doses of EPO within 5 hours of onset of symptoms in human stroke patients and showed an association between EPO administration and improved outcome. Applicant contends that Bianchi *et al.* showed that peripherally administered EPO prevented and reversed nerve dysfunction caused by streptozotocin (STZ)-induced diabetes in rats. Lastly, Applicant submits that Agnello *et al.*, used a rat model to induce experimental autoimmune encephalomyelitis (EAE) and demonstrated that EPO repairs the function of damage tissue.

Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. The instant Examples and the submitted references fail to teach that upon EPO administration, associative learning, memory or cognitive function is enhanced in mammals resulting from any type of tissue injury or damage. The instant specification teaches that when animals are

pre-treated with EPO or given EPO up to 3 hours after blunt trauma, the volume of brain necrosis was less than control. Ehrenreich *et al.* teach an association between EPO administration and an improved outcome in stoke patients. However, the teachings of Bianchi *et al.* (streptozotocin-induced diabetes in rats) and Agnello *et al.* (rat model for experimental autoimmune encephalomyelitis) are not applicable to EPO administration and enhanced associative learning, memory or cognitive function in mammals.

A disclosure of one example of damaged/injured excitable tissue (stroke) and enhanced function of damaged/injured excitable tissue, associative learning, memory or cognitive function in mammals upon EPO administration is not representative of a genus encompassing an unlimited number of conditions/diseases with damaged/injured excitable tissue and poor associative learning/memory. Similarly, a disclosure of two examples of damaged/injured excitable tissue (diabetic neuropathy and autoimmune encephalomyelitis) and enhanced function of damaged/injured excitable tissue upon EPO is not representative of a genus encompassing an unlimited number of conditions/diseases that have damaged or injured excitable tissue.

The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude"

granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 5-7 and 9 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7, 8, 11 and 12 of copending Application No. 09/717,053. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 5-7 and 9 of the instant application are drawn to a method of enhancing the function of normal, damage, or injured excitable tissue in a mammal, comprising administering peripherally to a mammal in need thereof a non-toxic effective amount of recombinant erythropoietin for enhancing excitable tissue function, wherein said administration comprises oral, topical, intraluminal or by inhalation or parental administration. Other claim limitations include wherein said parenteral administration is intravenous, wherein said administration is acute or chronic and wherein said EPO is administered at a dose greater than the dose necessary to maximally stimulate erythropoiesis.

Claims 1-5, 7, 8, 11 and 12 of copending Application No. 09/717,053 are drawn to a method for treating or protecting against injury or damage to heart

tissue in mammals, comprising administering peripherally to a mammal in need thereof a non-toxic amount of EPO effective for the protection or repair of the heart tissue. Other claim limitations include wherein said administration comprises oral, topical, intraluminal or by inhalation or parenteral administration, wherein said administration is acute or chronic, wherein said EPO is administered at a dose greater than the dose necessary to maximally stimulate erythropoiesis and wherein said injury or damage is the result of myocardial infarction, heart failure, cardiac arrest, etc.

The instant specification defines "excitable tissue" as neuronal and cardiac tissue (page 1, lines 13-14). The method of claim 5 of the instant application would encompass heart tissue. Thus the species of a method for treating or protecting against injury or damage to heart tissue in mammals, comprising administering peripherally to a mammal in need thereof a non-toxic amount of EPO effective for the protection or repair of the heart tissue renders the genus of a method of enhancing the function of normal, damage, or injured excitable tissue in a mammal, comprising administering peripherally to a mammal in need thereof a non-toxic effective amount of recombinant erythropoietin for enhancing excitable tissue function, obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 4-7 and 9 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims

15, 17, 18-22 of copending Application No. 09/716,960. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 4-7 and 9 of the instant application are drawn to a method of enhancing the function of normal, damage, or injured excitable tissue in a mammal, comprising administering peripherally to a mammal in need thereof a non-toxic effective amount of recombinant erythropoietin for enhancing excitable tissue function, wherein said excitable tissue is central nervous system tissue or peripheral nervous system tissue. Other claim limitations include wherein parenteral administration is intravenous, wherein said administration is acute or chronic and wherein said EPO is administered at a dose greater than the dose necessary to maximally stimulate erythropoiesis.

Claims 15, 17, 18-22 of copending Application No. 09/716,960 are drawn to a method for treating or protecting against injury or damage to neural tissue in a mammal, comprising administering peripherally to a mammal in need thereof an effective non-toxic amount of EPO for the treatment or protection of the neural tissue. Other claim limitations include wherein said neural tissue is central nervous system tissue or peripheral nervous tissue, administration comprises oral, topical, intraluminal or by inhalation or parental administration.

The instant specification defines "excitable tissue" as neuronal and cardiac tissue (page 1, lines 13-14). The method of claim 5 of the instant application would encompass neural tissue. Furthermore, the method of claim 4 of the instant application is drawn to excitable tissue of either the central nervous system tissue or peripheral nervous system tissue.

Thus the species of a method for treating or protecting against injury or damage to neural tissue in mammals, comprising administering peripherally to a mammal in need thereof a non-toxic amount of EPO effective for the treatment or protection of the neural tissue renders the genus of a method of enhancing the function of normal, damage, or injured excitable tissue in a mammal, comprising administering peripherally to a mammal in need thereof a non-toxic effective amount of recombinant erythropoietin for enhancing excitable tissue function, wherein said excitable tissue is central nervous system tissue or peripheral nervous system AND a method of enhancing the function of normal, damage, or injured excitable tissue in a mammal, comprising administering peripherally to a mammal in need thereof a non-toxic effective amount of recombinant erythropoietin for enhancing excitable tissue function, obvious.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth C. Kemmerer

RMD
3/29/05

ELIZABETH KEMMERER
PRIMARY EXAMINER